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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,143	05/14/2001	Karl F. Gruber	530-014	1123

7590

09/16/2002

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EXAMINER
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COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/16/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/855,143

Applicant(s)

GRUBER ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 13-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group II, claims 9-12 in Paper No. 5 is acknowledged.

***Claim Objections***

2. Claim 9 is objected to because of the following informalities: Claim 9, line 4 "concentration" should be --concentrating--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and indefinite because of the use of an acronym: i.e. MSIA. Although the term may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The term should be defined in its first instance.

Claim 11, line 2 "the presence of mass shifted variants" there is insufficient antecedent basis for this limitation. See also deficiencies in claim 12.

Claim 11, line 2 "mass shifted variants" is vague. It is unclear what applicant is trying to encompass. There is no definition provided for the term in the specification.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Bieber et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158).

Bieber et al disclose a method to determine an analyte by capturing and isolating an antigen. Bieber et al disclose providing a filter pipet tip (MSIA-tip) for retaining an affinity reagent-antigen complex (Figure 1 and description of Figure 1). Bieber et al disclose incubating antibodies covalently immobilized to a solid support with an antigen-containing sample. Bieber et al disclose MSIA reagent comprised of beads having protein A (affinity ligand) on their surface and affinity purified rabbit antibodies as MSI A reagents. Bieber et al disclose that after incubation and the formation of antibody/antigen complexes, the complexes are washed and then the antigen is eluted onto a mass spectrometer probe tip using a solution of MALDI matrix. Bieber et al. further disclose that after the antigen is eluted that Time-of-flight mass spectrometry is performed (page 1153 col 2, see also Experimental Section). Bieber et al also disclose that a single assay can be used to screen biological systems for the presence of multiple, mass-resolved antigens. Bieber et al also disclose that antigen signals are

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observed to determine the presence and amount of an antigen or its antigen variant (p. 1158).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bieber et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158) in view of Ogura et al (UK Patent 2,030,294).

See above for teachings of Bieber et al.

Bieber et al differ from the instant invention in failing to teach the use of anti-human  $\beta$ 2-microglobulin antibody as an affinity reagent.

Ogura et al disclose anti-human  $\beta$ 2-microglobulin coated on the surface of a solid support. Ogura et al disclose this anti-human  $\beta$ 2-microglobulin allows for a composition for use in the qualitative or quantitative determination of human  $\beta$ 2-microglobulin, which has superior storage stability and which can rapidly give reliable results with good reproducibility and a high degree of accuracy without being hampered by other proteins that may be contained in an assay sample (p. 1 and abstract).

It would have been obvious to one of ordinary skill in the art to substitute the anti-human  $\beta$ 2-microglobulin antibody as taught by Ogura et al for the affinity purified rabbit

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antibodies of Bieber et al because Ogura et al shows that this anti- human  $\beta$ 2-microglobulin antibody allows for a composition for use in the qualitative or quantitative determination of human  $\beta$ 2-microglobulin, which has superior storage stability and which can rapidly give reliable results with good reproducibility and a high degree of accuracy without being hampered by other proteins that may be contained in an assay sample.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
September 9, 2002



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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09/09/02